

INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				ATTY DOCKET NO. 98-PO151 US2	SERIAL NO. 10/789,398		
				Kathleen M. Miller et al.			
				FILING 02/27/04	GROUP 3738		
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
/TJS/	1.	4,054,139	10/18/77	Crossley	128	260	
	2.	4,240,163	12/23/80	Galin	3	13	
	3.	4,472,327	9/18/84	Neefe	264	1.9	
	4.	4,603,152	7/29/86	Laurin et al.	604	265	
	5.	4,723,950	2/9/88	Lee	604	322	
	6.	4,731,080	3/15/88	Galin	623	6	
	7.	4,853,978	8/8/89	Stockum	2	167	
	8.	4,902,503	2/20/90	Umemura et al.	424	83	
	9.	4,923,450	5/8/90	Maeda et al.	604	265	
	10.	4,933,178	6/12/90	Capelli	424	78	
/TJS/	11.	4,946,899	8/7/90	Kennedy et al.	525	244	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
/TJS/	1.	WO 97/14447	4/24/97	PCT	A61L 27	00	✓
/TJS/	2.	WO 99/47595	9/23/99	PCT	CO8K 3	00	✓
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
/TJS/	1.	Swartz, R., et al., "Biofilm Formation on Peritoneal Catheters Does Not Require the Presence of Infection," <i>ASAIO Trans.</i> , Vol. 37, no. 4, Oct.-Dec. 1991, pp. 626-634.					
/TJS/	2.	Richards, G.K., et al., "Comparative Rates of Antibiotic Action Against <i>Staphylococcus epidermidis</i> Biofilms," <i>ASAIO Trans.</i> , Vol. 37, no. 3, Jul.-Sept. 1991, pp. M160-162.					
EXAMINER /Thomas J Sweet/ (08/22/2007)				DATE CONSIDERED			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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/TJS/	12.	4,978,391	12/18/90	Jones	106	35	
	13	5,080,892	1/14/92	Yamamori et al.	424	78.09	
	14.	5,091,205	2/25/92	Fan	427	2	
	15.	5,091,442	2/25/92	Milner	523	122	
	16.	5,098,379	3/24/92	Conway et al.	604	51	
	17.	5,102,401	4/7/92	Lambert et al.	604	264	
	18.	5,102,402	4/7/92	Dror et al.	604	265	
	19.	5,130,159	7/14/92	Shlenker et al.	427	2	
↓	20.	5,135,516	8/4/92	Sahatjian et al.	604	265	
/TJS/	21.	5,137,671	8/11/92	Conway et al.	264	130	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

/TJS/	3.	Stamm, Walter E., "Catheter-Associated Urinary Tract Infections: Epidemiology, Pathogenesis, and Prevention," <i>American Journal of Medicine</i> , Vol. 91, no. 3B, Sept. 1991, pp. 65S-71S.
/TJS/	4.	Golomb, Gershon, et al., "Prevention of Bacterial Colonization on Polyurethane <i>in vitro</i> by Incorporated Antibacterial Agent," <i>Journal of Biomedical Materials Research</i> , Vol. 25, no. 8, Aug. 1991, pp. 937-952.

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/TJS/	22	5,165,952	11/24/92	Solomon et al.	427	2	
	23.	5,171,318	12/15/92	Gibson et al.	623	5	
	24.	5,178,870	1/12/93	Schaeken et al.	424	405	
	25.	5,217,493	6/8/93	Raad et al.	623	11	
	26.	5,261,896	11/16/93	Conway et al.	604	265	
	27.	5,272,012	12/21/93	Opolski	428	423.1	
	28.	5,304,121	4/19/94	Sahatjian	604	53	
	29.	5,328,954	7/12/94	Sarangapani	524	589	
	30.	5,344,411	9/6/94	Domb et al.	604	265	
▼	31.	5,360,415	11/1/94	Yabushita et al.	604	265	
/TJS/	32.	5,362,754	11/8/94	Raad et al.	514	566	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

/TJS/	5.	Mulhall, Anne, "Biofilms and Urethral Catheter Infections," <i>Nursing Standard</i> , Vol. 5, no. 18, Jan. 23-29, 1991, pp. 26-28.
/TJS/	6.	Chang, Chung Che, et al., "Effect of <i>Staphylococcus epidermidis</i> on Adherence of <i>Pseudomonas aeruginosa</i> and <i>Proteus mirabilis</i> to Polymethyl Methacrylate (PMMA) and Gentamicin-Containing PMMA," <i>Journal of Orthopaedic Research</i> , Vol. 9, no. 2, Mar. 1991, pp. 284-288.

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/TJS/	33.	5,366,505	11/22/94	Farber	623	11	
	34..	5,370,681	12/6/94	Herweck et al.	623	1	
	35.	5,389,314	2/14/95	Wang	264	25	
	36.	5,409,012	4/25/95	Sahatjian	128	749	
	37.	5,462,644	10/31/95	Woodson	204	131	
	38.	5,599,298	2/4/97	Sahatjian	604	49	
	39.	5,607,683	3/4/97	Capelli	424	405	
	40.	5,611,354	3/18/97	Alleyne	128	846	
	41.	5,616,119	4/1/97	Davis	604	19	
↓	42.	5,624,704	4/29/97	Darouiche et al.	427	2.24	
/TJS/	43.	5,643,207	7/1/97	Rise	604	93	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
/TJS/	7.	Liedberg, H., et al., "Pseudomonas aeruginosa: Adherence to and Growth on Different Urinary Catheter Coatings," <i>International Urology and Nephrology</i> , Vol. 22, no. 5, 1990, pp. 487-492.					
/TJS/	8.	Anwar, Hosmin, et al., "Testing the Susceptibility of Bacteria in Biofilms to Antibacterial Agents," <i>Antimicrobial Agents and Chemotherapy</i> , Vo. 34, no. 3, 1990, pp. 2043-2046,					
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/TJS/	44.	5,679,399	10/21/97	Shlenker et al.	427	2.3	
	45.	5,707,366	1/13/98	Solomon et al.	604	265	
	46.	5,716,406	2/10/98	Farber	623	11	
	47.	5,741,331	4/21/98	Pinchuk	623	11	
	48.	5,772,640	6/30/98	Modak et al.	604	265	
	49.	5,853,745	12/29/98	Darouiche	424	423	
	50.	5,902,283	5/11/99	Darouiche et al.	604	265	
	51.	6,083,208	7/4/2000	Modak et al.	604	265	
↓	52.	6,106,505	8/22/2000	Modak et al.	604	265	
/TJS/	53.	09/734,639		Pinchuk et al.			12/12/00
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
/TJS/	9.	Dunne, W. Michael Jr., "Effects of Subinhibitory Concentrations of Vancomycin or Cefamandole on Biofilm Production by Coagulase-Negative Staphylococci," <i>Antimicrobial Agents and Chemotherapy</i> , Vol. 34, no. 3, Mar. 1990, pp. 390-393.					
/TJS/	10.	Doughterty, Steven H., et al., "Endogenous Factors Contributing to Prosthetic Device Infections," <i>Infectious Disease Clinics of North America</i> , Vol. 3, no. 2, June 1989, pp. 199-209.					
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INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>			Docket Number (Optional) 98-PO151 US2	Application Number 10/789,398
			Applicant(s) Kathleen M. Miller et al.	
			Filing Date 02/27/04	Group Art Unit 3738
*EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>			
/TJS/	11.	Speer, Anthony G., et al., "Biliary Stent Blockage with Bacterial Biofilm," <i>Annals of Internal Medicine</i> , Vol. 108, no. 4, Apr. 1998, pp. 546-553		
	12.	Liedberg, H., et al., "Silver Coating of Urinary Catheters Prevents Adherence and Growth of <i>Pseudomonas Aeruginosa</i> ," <i>Urological Research</i> , Vol. 17, no. 6, 1989, pp. 357-358.		
	13.	Ramsay, J.W.A., et al., "Biofilms, Bacteria, and Bladder Catheters: A Clinical Study," <i>British Journal of Urology</i> , Vol. 64, no. 4, Oct. 1989, pp. 395-398.		
	14.	Farber, Bruce F., et al., "The Use of Nonsteroidal Antiinflammatory Drugs to Prevent Adherence of <i>Staphylococcus epidermidis</i> to Medical Polymers," <i>Journal of Infectious Diseases</i> , Vol. 166, no. 4, Oct., 1992, pp. 861-865.		
	15.	Farber, Bruce F., et al., " <i>Staphylococcus epidermidis</i> Extracted Slime Inhibits the Antimicrobial Action of Glycopeptide Antibiotics," <i>Journal of Infectious Diseases</i> , Vo., 161, no.1, Jan. 1990, pp. 37-40.		
	16.	Donnenfeld, E.D., et al., "Biofilm and Bacterial Adherence Inhibition with Sodium Salicylate," <i>Investigative Ophthalmology & Visual Science</i> , Vol. 35, no. 4, 1994, p. 2164.		
	17.	Farber, B.F., et al., " <i>Staphylococcus aureus</i> Extracted Polysaccharide Interferes with the Antimicrobial Action of Glycopeptide Antibiotics," <i>Clinical Research</i> , Vol. 38, no. 2, 1990, p. 428A.		
	18.	Farber, B.F., et al., "Extracted <i>S. epidermidis</i> Slime Interferes with the Antimicrobial Action of Glycopeptide Antibiotics," <i>Clinical Research</i> , Vol. 37, no. 2, 1990, p. 428A.		
	19.	Farber, B.F., et al., "Unique Properties of <i>S. epidermidis</i> Extractable Polysaccharide Slime (SEEP)," <i>Clinical Research</i> , Vol. 36, no. 3, 1988, p. 455A.		
	20.	Teichberg, Saul, et al., "Salicylic Acid Decreases Extracellular Biofilm Production by <i>Staphylococcus epidermidis</i> : Electron Microscope Analysis," <i>Journal of Infectious Diseases</i> , Vol. 167, no. 6, 1993, pp. 1501-1503.		
/TJS/	21.	Farber, Bruce F., et al., "A Novel Antibiofilm Technology for Contact Lens Solutions," <i>Ophthalmology</i> , Vol. 102, no. 5, May 1995, pp. 831-836.		
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		Applicant(s) Kathleen M. Miller	
		Filing Date 02/27/04	Group Art Unit 3738
*EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>		
/TJS/	22.	Roberts, E.L., et al., "The Role of Sodium Salicylate in the Prevention of the Adherence of Acanthamoeba Castellanii to Unworn Contact Lenses," <i>Investigative Ophthalmology & Visual Science</i> , Vol. 35, no. 4, 1994, p. 2150.	
	23.	Donnenfeld, Eric D., et al., "Controlled Evaluation of a Bandage Contact Lens and a Topical Nonsteroidal Antiinflammatory Drug in Treating Traumatic Corneal Abrasions," <i>Ophthalmology</i> , Vol. 102, no. 6, June 1995, pp. 979-984.	
	24.	Costerton, J. William, et al., "Bacterial Biofilms in Nature and Disease," <i>Annual Review of Microbiology</i> , Vol. 41, 1987, pp. 435-464.	
	25.	Parsons, C. Lowell, et al., "Inhibition of Sodium Urate Crystal Adherence to Bladder Surface by Polysaccharide," <i>Journal of Urology</i> , Vol. 134, no. 3, Sept. 1985, pp. 614-616.	
	26.	Kingston, D., et al., "Self-disinfecting Plastics for Intravenous Catheters and Prosthetic Inserts," <i>Journal of Hygiene, Cambridge</i> , Vol. 96, 1986, pp. 185-198.	
↓	27.	Speer, A.G., et al., "The Role of Bacterial Biofilm in Clogging of Biliary Stents," Dept. Gastroenterology, Middlesex Hospital, London UK, Dept. Biology, University of Calgary, Alberta, Canada.	
/TJS/	28.	Sherman, Stuart, et al., "Stent-induced Pancreatic Ductal and Parenchymal Changes: Correlation of Endoscopic Ultrasound with ERCP," <i>Gastrointestinal Endoscopy</i> , Vol. 44, no. 3, 1996, pp. 276-282.	
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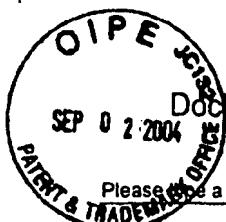
Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
Sheet		1	of	1	Attorney Docket Number
Application Number		107789-398			
Filing Date		02/27/04			
First Named Inventor		Kathleen M. Miller et al.			
Group Art Unit		3738			
Examiner Name		Unassigned			
98-PO151 US2					

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office ²	Number ³	Class/Subclass			
/TJS/	3	EP	0 328 421 A2	A61 L 29/00	Trustees of Columbia University in the City of New York	08/16/1989	
↓	4	EP	0 379 271 A2	A61L 29/00	Becton Dickinson and Company	07/25/1990	
	5	WO	01/21229 A1	A61L 31/16	Clarence C. Lee	03/29/2001	
/TJS/	6	WO	93/10847	A61M 25/00	North Shore University Hospital Research Corporation	06/10/1993	

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¹ Unique citation designation number. ² See Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English Language Translation is attached.



Docket No.: 98-P0151US2

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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/789,398
				Filing Date	02/27/2004
				First Named Inventor	Kathleen M. Miller et al.
				Group Art Unit	3738
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	98-P0151US2

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office ²	Number ³	Class/Subclass			
/TJS/	1.	EP	0970711 A2	A61L 31/10	Ethicon, Inc.	01/12/2000	
V	2.	WO	01/03607 A2	A61F 2/00	Scimed Life Systems, Inc.	01/18/2001	
/TJS/	3.	DE	3347660 A1	C08K 5/00	Troponwerke GmbH & Co. KG	07/11/1985	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/789,398
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				First Named Inventor	Kathleen M. Miller
				Group Art Unit	3738
				Confirmation No.	4925
				Examiner Name	Unassigned
Sheet	1	of	3	Attorney Docket Number	98-P0151US2

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		Number	Class/Subclass		
/TJS/	1.	2004/0249441 A1	623/1.15	Miller et al.	12/09/2004
	2.	2004/0166102 A1	424/93.45	Darouiche et al.	08/26/2004
	3.	2004/0166094 A1	424/93.4	Darouiche et al.	08/26/2004
	4.	2003/0224033 A1	424/423	Li et al.	12/04/2003
	5.	2003/0199993 A1	623/23.75	Gellman et al.	10/23/2003
	6.	2003/0153983 A1	623/23.7	Miller et al.	08/14/2003
	7.	2003/0018306 A1	604/265	Bucay-Couto et al.	01/23/2003
	8.	2002/0031601 A1	427/2.1	Darouiche et al.	03/14/2002
	9.	2004/0208908 A1	424/423	Modak et al.	10/21/2004
↓	10.	2003/0203991 A1	523/334	Schottman et al.	10/30/2003
	11.	2003/0078242 A1	514/150	Raad et al.	04/24/2003
/TJS/	12.	2003/0024534 A1	128/846	Silvestri et al.	02/06/2003

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Sheet	2	of	3	Application Number	10/789,398
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				Group Art Unit	3738
				Confirmation No.	4925
				Examiner Name	Unassigned
				Attorney Docket Number	98-P0151US2

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
/TJS/	1.	Percuflex® Tail Plus™ Tapered Ureteral Stent. Boston Scientific. Urology. http://www.bostonscientific.com/med_specialty/deviceDetail.jhtml?task=tskBasicDevice.jhtml&s.2/24/2004 download.			
	2.	H.N. BHARGAVA ET AL., "Triclosan: Applications and Safety," <i>American Journal of Infection Control</i> , vol. 24(3), June 1996, pp. 209-218.			
	3.	RHONDA D. JONES ET AL., "Triclosan: A Review of Effectiveness and Safety in Health Care Settings," <i>American Journal of Infection Control</i> , vol. 28(2), Apr. 2000, pp. 184-196.			
	4.	J. REGOS ET AL., "Antimicrobial Spectrum of Triclosan, a Broad-Spectrum Antimicrobial Agent for Topical Application. II. Comparison with Some Other Antimicrobial Agents," <i>Dermatologica</i> , vol. 158, 1979, pp. 72-79.			
	5.	STEPHEN ROTHENBURGER ET AL., "In Vitro Antimicrobial Evaluation of Coated VICRYL* Plus Antibacterial Suture (Coated Polyglactin 910 with Triclosan) Using Zone of Inhibition Assays," <i>Surgical Infections</i> , vol. 3, supplement, 2002, pp. S-79-S87.			
	6.	EDWARD S. WONG ET AL., Guideline for Prevention of Catheter-associated Urinary Tract Infections. http://www.cdc.gov . n.d. but before the date of this application.			
	7.	ALLAN RONALD, "The Etiology of Urinary Tract Infection: Traditional and Emerging Pathogens," <i>Dis. Mon.</i> , vol. 49, 2003, pp. 71-82.			
	8.	ALAIN MEYRIER, Urinary Tract Infections, Vol. II, Chapter 7 of <i>The Schrier Atlas of Diseases of the Kidney</i> , ed. Robert W. Schrier, 1999.			
↓	9.	DONALD P. GRIFFITH ET AL., "Urease: The Primary Cause of Infection-Induced Kidney Stones," <i>Investigative Urology</i> , vol. 13(5), March 1976, pp. 346-350.			
/TJS/	10.	D.J. STICKLER ET AL., "Control of Encrustation and Blockage of Foley Catheters," <i>The Lancet</i> , vol. 361, April 26, 2003, pp. 1435-1437.			

Examiner Signature	/Thomas J Sweet/ (08/22/2007)	Date Considered	
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
Sheet	3	of	3	Application Number	10/789,398
				Filing Date	02/27/2004
				First Named Inventor	Kathleen M. Miller
				Group Art Unit	3738
				Confirmation No.	4925
				Examiner Name	Unassigned
				Attorney Docket Number	98-P0151US2

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
/TJS/	11.	Ciba Specialty Chemicals. Ciba® IRGASAN® DP 300, Ciba® IRGACARE® MP Antimicrobials. Toxicological and ecological data; Official registrations. Jan. 2003. 16 pages.		
/TJS/	12.	Ciba Specialty Chemicals. Ciba® IRGASAN® DP 300, Ciba® IRGACARE® MP. Antimicrobial active ingredient for personal care products. 2001. 16 pages.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10/789,398
		Filing Date	02/27/2004
		First Named Inventor	Miller et al.
		Group Art Unit	3738
		Confirmation No.	4925
		Examiner Name	Unassigned
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Sheet	1		

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Substitute for form 1448A/PTO				Complete if Known	
				Application Number	10/789,398
				Filing Date	02/27/2004
				First Named Inventor	Kathleen M. Miller
				Group Art Unit	3738
				Examiner Name	Thomas Sweet
Sheet	1	of	1	Attorney Docket Number	98-P0151US2

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Issue Date MM-DD-YYYY
		Number	Class/Subclass		
/TJS/	1.	6,887,270 B2	623/11.11	Miller et al.	05-03-2005
/TJS/	2.	6,921,390 B2	604/265	Bucay-Couto et al.	07-26-2005

Examiner Initials*	Cite No. ¹	U.S. Patent Publication		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Class/Subclass		
/TJS/	1.	2003/0224033 A1	424/423	Li et al.	12-04-2003
	2.	2004/0022824 A1	424/423	Li et al.	02-05-2004
	3.	2005/0161859 A1	264/209.1	Miller et al.	07-28-2005
↓	4.	2005/0271698 A1	424/423	Bucay-Couto et al.	12-08-2005
	5.	2005/0255230 A1	427/2.1	Clerc et al.	11-17-2005
/TJS/	6.	2006/0264912 A1	604/891.1	McIntyre et al.	11-23-2006

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